Kansas Medical Assistance

DRUG UTILIZATION REVIEW BOARD

Meeting Minutes, Open Session

July 14, 2004

DRUG UTILIZATION REVIEW BOARD Meeting Minutes, Open Session EDS/White Lakes Mall Wichita/Kansas City Room Topeka, Kansas July 14, 2004	**Members Present:** Michael Burke, M.D., Ph.D., Chair; R. Kevin Bryant, M.D., CMD; Dennis Grauer, Ph.D.; John Lowdermilk, R.Ph.; Brenda Schewe, M.D.; Roger Unruh, D.O.; Kevin Waite, PharmD **SRS Staff Present:** Nialson Lee, B.S.N, M.H.A.; Mary Obley, R.Ph.; Vicki Schmidt, R.Ph., DUR Program Director; Erica Miller **EDS Staff Present:** Nicole Garcia, R.N.; Bernice Shelton, Chalen Reed, R.Ph.; Debra Quintanilla, R.N.	**Representatives:** Bruce Hodges, M.D. (Suburban Family Physician), Patty Dick (Arthritis Foundation), Robert Calder, M.D. (Merck), Marc Claussen (Watson Pharma), Tammie Capps (Purdue), Rhonda Clark (Purdue), Stephanie Miller (Amgen), Jennifer Leeth (TAP), Bob Marshall (Novartis), Diana Morasch (AstraZeneca), Jillmarie Yanchick (Pfizer), Mike Hutfles (Kansas Governmental Consulting), Bruce Steinberg (Aventis Pharmaceuticals), Nancy Zogleman (Pfizer), Susan Williams (Sepracor), Arnie Bazemore (Sepracor),Ann Gustafson (GSK), Dave Hanson (Pfizer), Pete Roth (Forest), Bob Bollinger (Forest), Lon Lowrey (Novartis), Barbara Belcher (Merck), Jim Baumann (Pfizer), Candie Phipps (Boehringer Ingelheim), Shawn Evans (Bristol-Myers Squibb), Carol Curtis (AstraZeneca), Pat Hubbell (Pharma)

TOPIC	DISCUSSION	DECISION/ACTION
I. Call to Order	• Dr. Michael Burke, Chair, called the Open Meeting of the Drug Utilization Review Board to order at 9:35a.m.	
II. Review and Approval of May 12, 2004, Meeting Minutes	• One correction was made to the May 12, 2004 meeting minutes. Page 1, under Decision/Action change Mrs. Bryant to Dr. Bryant and on page 4	• A motion to approve the minutes with the corrections was made by Dr. Schewe and seconded by Dr. Waite. The motion carried

	under Discussion change AO to OA.	unanimously by roll call.
TOPIC	**DISCUSSION**	**DECISION/ACTION**
III. Old Business **A. PA Unit Report**	• Deb Quintanilla, R.N. presented information regarding the Prior Authorization Unit. • Dr. Grauer asked about the prior authorizations (PA) that take numerous days. Deb stated that in the case of one of the Cox-2 prior authorizations that were approved on day 108 the PA unit received the information on February 27, 2003 and was told by the pharmacy that the physician's office would send the additional information. On March 10, 2003 the PA unit received the additional information from the physician's office. At that time the patient did not meet the criteria, so it was denied. On July 29, 2003 the physician sent additional documentation and the patient met the criteria. In cases like this the claim is pulled from denied status and is thought of as a reconsideration. Therefore, to the PA unit the patient was approved on day 108 even though once all the information was received it was approved in less than 24 hours. It was a similar case on the second PA that was approved on the 108th day. Deb also pointed out that the document that was submitted to the legislature contained "average" days. • Dr. Burke asked what information is missing when the PA is denied for missing information. Deb stated that most are missing the same information. There are numerous physicians or pharmacists that don't put a check mark in one of the boxes or they don't sign the form. Dr. Burke asked if the PA unit calls that day to get the missing information. Deb stated that the unit calls the day the PA is received.	

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PA Unit Report – Con't **Public Comment**	• Jim Baumann (Pfizer) asked why the PA nurses are split between the PDL and non-PDL drugs. Deb stated that all the nurses are capable of reviewing PDL and non-PDL drugs. They split them up to help keep things organized internally. • Jim Baumann (Pfizer) stated that he was under the impression that the DUR Board wanted inadequate response marked and wasn't aware that the physician had to write out what the inadequate response was. Deb stated that they need the physician to list what the inadequate response was. • Tammie Capps stated that all PAs have to be approved or denied within 24 hours. Are the patients that have PAs in pending status allowed to receive 48 hours worth of the medication? Deb stated that the patients that are stuck in pending are approved or denied that same day. If they can get the needed information from the physician it will be approved that same day. • Dr. Unruh stated that it is a little redundant to have to check inadequate response and have to list that the blood pressure is still high, when it is obvious that would be the inadequate response with a blood pressure medication. • Bruce Steinburg (Aventis) asked if it is identified what drugs can be PA'd over the phone and which have to be mailed or faxed in with the information. Deb stated that it is listed on the Fact Sheet that was handed out. • Vicki stated that yesterday Dr. Burke called her and informed her that there is a Rheumatologist that is having problems getting a PA approved.	
TOPIC	**DISCUSSION**	**DECISION/ACTION**

PA Unit Report – Con't	After speaking to the Rheumatologist and looking up the PA it turns out the Rheumatologist was trying to get Enbrel approved. The first prior authorization that was sent in was originally listed as trying to get Bextra and most of the numbers were wrong as well. For example, the physician identification number was incorrect. All the corrections were eventually made, the PA was approved, and the drug was dispensed, but no one informed the physician. Vicki then requested for the pharmaceutical reps to help inform the providers that they should list their phone numbers on the bottom of the form if they would like to be notified when the prior authorization is approved. Vicki also suggested if anyone hears of any problems to please let us know, so we can research the issues. Dr. Burke asked if it helps when the providers call. Vicki said yes. Dr. Burke asked if there is a phone number the providers can call. Vicki stated that they can call the pharmacy help desk toll free (866-405-5200).	
B. Cox-2 Inhibitors **Discussion of Prior Authorization Criteria** **Public Comment**	• Mary reviewed the hand out regarding the past DUR meetings. Mary pointed out that in March of 2002, a hard edit was placed on Cox-2s. • Dr. Burke requested getting a PA set up that will cover numerous diagnosis's for Cox-2s, so they don't have to re-review this class in a couple months when a new indication is released. Dr. Burke also pointed out that on the chart regarding other States, step therapy is not listed on all of the States that use it, Kansas does not allow step therapy. • Dr. Jillmarie Yanchich (Pfizer) presented	
TOPIC	**DISCUSSION**	**DECISION/ACTION**

Cox-2 Inhibitors – Con't	information to the DUR Board regarding Cox-2 Inhibitors. • Dr. Bruce Hodges (Suburban Family Physician) presented information to the DUR Board regarding Cox-2 Inhibitors and nursing homes. He also pointed out that the age should be changed to 55 in his opinion. Dr. Hodges (Suburban Family Physician) stated that he received a PA form for a patient he prescribed a Cox-2 for and this patient is 85 years old. Deb pointed out that the PA form was probably sent by the pharmacy. She also stated if the pharmacy would have submitted the drug without filling out the PA it would have been approved. Dr. Lowdermilk stated it is obvious this pharmacy does not know the rules. Vicki asked what EDS's policy is when they receive a PA for a drug that does not need it. Deb stated that the PA unit will call the pharmacy. She also stated that this is an educational training issue and the physician can also call the pharmacy if they know the PA is not needed. Dr. Hodges (Suburban Family Physician) asked how providers are supposed to know this information. Mary stated that the State can try and make the forms easier, but this information is available. Dr. Hodges (Suburban Family Physician) stated that he did not realize the PA form he received was sent to him by the pharmacy. • Dr. Burke stated that we should probably revisit the format of the forms. Nancy Zogelman (Pfizer) suggested listing the toll free number on the top of both of the forms. Nialson stated that the State would look into it. Dr. Grauer suggested listing the criteria on the forms as well.	
TOPIC	**DISCUSSION**	**DECISION/ACTION**

Cox-2 Inhibitors – Con't	• Dr. Robert Caulder (Merck) presented information to the DUR Board regarding Cox-2Inhibitors. He stated that SRS should not wait until the patient has a GI problem before allowing them to receive a Cox-2 Inhibitor. He also reviewed the VIGOR study. • Dr. Burke reviewed the results of the Evidence-based Policy (EPC) report and reviewed the other States PA requirements. He also stated that we should try and have a PA form that does not list all the medical conditions. Suggestions include listing patients that are less than 65 with anti-inflammatory analgesia and list GI diagnosis. Dr. Schewe stated that will not take care of the Rheumatoid Arthritis (RA) and Osteoarthritis (OA). Mary stated that the States that exempt OA and RA have step therapy, so they are still required to fail on a NSAID before they can receive a Cox-2. Chris Johnson (Heritage Information Systems) explained Missouri's PA process. • Nancy Zogelman (Pfizer) requested that the PA Unit use a form similar to the form Pfizer provided, as this would make things simpler. Dr. Burke pointed out handout number 10 under the SRS portion. Dr. Burke reviewed the charts and graphs regarding cost and prescriptions provided by SRS. • Dr. Schewe asked if in 6 months the cost of GI bleeds will be going up if we don't allow them to receive a Cox-2 Inhibitor prior to the start of GI problems. Mary stated that the State does not have that information. She then pointed out handout number 11 under the SRS section.	
TOPIC	**DISCUSSION**	**DECISION/ACTION**

Cox-2 Inhibitors – Con't	• Dr. Burke suggested trying to get clinical data regarding GI bleeds. • Barbara Belcher (Merck) stated that if we are going to pull clinical data on GI problems we need to pull information on GI naïve patients. For example, if the patient has a ulcer did it occur before or after being placed on a Cox-2. Most likely we will not be able to find a GI naïve patient with our PA criteria. • The DUR Board discussed possible criteria for Cox-2 Inhibitors. • Dr. Burke clarified that patients with migraines can receive a Cox-2 if they have a GI problem. The DUR Board agreed. Dr. Burke stated we could keep the old criteria and revisit and look at the economics. He also questioned why this wasn't looked at in the PDL meeting. Mary stated that we could take this to the PDL and pointed out that there are still patients with GI problems while on a Cox-2. The VA still classifies Cox-2 Inhibitors as a second line therapy.	
DUR Board Recommendation	• With no further discussion, a motion was placed before the Board.	• A motion was made by Dr. Grauer and seconded by Dr Waite to amend the SRS recommended Cox-2 Inhibitor criteria to: No Prior Authorization is required if consumer is > or = to age 65 on Date of Service. Prior Authorization is required if consumer is < age 65 on the Data of Service and requires anti-inflammatory analgesia with one or more of the following: • Documented history of GI bleed, gastric duodenal ulcer, peptic ulcer disease (PUD), erosive or NSAID-associated gastritis, GERD, or hiatal hernia. Only need to document any of the above.
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Cox-2 Inhibitors – Con't	• It was then discussed whether a motion should be made to change the wording of the form by adding anti- inflammatory analgesia. Vicki stated that the Board does not need to make a motion. • Mary asked if the final decision was to exempt patients over the age of 65 and OA and RA. DUR Board stated that is correct. Barbara Belcher (Merck) asked if they eliminated migraines from the PA. Dr. Burke stated that	• Documented history of GI irritation. Must specify symptoms of the irritation. • Concurrent use of anticoagulants (such as warfarin, heparin) or oral corticosteroids in last 31 days. Must list medication. PA requests for consumer taking concomitant anticoagulant therapy, current criteria notes Warfarin. The following exclusions under anticoagulants should include: Warfarin (Coumadin®), Plavix®, and Ticlodipine (Ticlid®). It does NOT include Aspirin. PA request for consumers taking corticosteroid therapy (ie. Advair® or similar inhalers) does not meet the current criteria which is specific for concomitant oral corticosteroid therapy. • Familial Adenomatous Polyposis (FAP), *Celebrex Only* • Diagnosis of Osteoarthritis (OA). • Diagnosis of Rheumatoid Arthritis (RA). • Consumer at high risk for colorectal cancer. (High Risk defined as: 80-100% lifetime risk of developing colorectal cancer due to a germline mutation with genetic predisposition. (Hawk, Dubois,, 2001:37th Annual Meeting of the American Society of Clinical Oncology). The motion carried unanimously by roll call.

Cox-2 Inhibitors – Con't	was correct, it has been changed to patients with anti-inflammatory analgesia. The patients with migraines can receive a Cox-2 if they have GI problems.	
IV. New Business **A. Discussion/Approval of PDL and Resulting PA Criteria for Non-preferred Drugs** **1. Proton Pump Inhibitors** **a. PDL Advisory Committee Recommendations**	• Dr. Burke stated that the PDL Committee found clinical equivalence in the Proton Pump Inhibitors class of drugs.	
b. SRS Proposal for Preferred Drugs and PA Criteria	• Mary stated that the recommendation from SRS is for Lansoprazole (Prevacid®), Esomeprazole (Nexium®), and Omeprazole OTC (Prilosec® OTC) to be the preferred PPI's, and PA required for Rabeprazole (Aciphex®), Omeprazole(Prilosec® & generic equivalents), and Pantoprazole (Protonix®, ProtonixIV®).	
c. Public Comment	• No public comment.	
d. Discussion	• Dr. Burke asked if they should make any modifications to the form. Dr. Schewe stated that it is redundant to have you mark inadequate response and then have to specify. Dr. Schewe requested removing "please specify" on the inadequate response portion of the form. Dr. Waite agrees.	
e. DUR Board Recommendations	• With no further Board discussion, a motion was placed before the Board.	• A motion was made by Dr. Bryant and seconded by Dr. Schewe to accept the SRS recommendation for Lansoprazole (Pravacid®), Esomeprazole (Nexium®), and Omeprazole OTC (Prilosec® OTC) to be the Preferred PPIs, and PA required for Rabeprazole (Aciphex®), Omeprazole
TOPIC	**DISCUSSION**	**DECISION/ACTION**

Proton Pump Inhibitors-Continued		(Prilosec® & generic equivalents), and Pantoprazole (Protonix®, ProtonixIV®) with PA criteria of medical intolerance to Preferred Drug, or inadequate response to Preferred Drug, or absence of appropriate formulation or indication of the drug. It was also decided to remove "please specify" from the inadequate response portion of the PA form. The motion carried unanimously by roll call.
2. HMG-CoA Reductase Inhibitors **a. PDL Advisory Committee Recommendations**	• Dr. Burke stated that the PDL Committee found Atorvastatin, Simvastatin, Pravastatin, and Rosuvastatin clinically equivalent and the most potent Statins. Pravastatin should be available for special populations when drug interactions are an issue. Fluvastatin and Lovastatin are not preferred Statins and are not clinically equivalent.	
b. SRS Proposal for Preferred Drugs and PA Criteria	• Mary stated that the recommendation from SRS is for Atorvastatin (Lipitor) and Simvastatin (Zocor®) to be the Preferred HMG-CoA Reductase Inhibitors-Statins, and PA required for Fluvastatin (Lescol®), Lovastatin (Mevacor®, Altacor®, generic equivalents), Pravastatin (Pravachol®, Pravigard Pac®), and Rosuvastatin (Crestor®).	
c. Public Comment	• No public comment.	
d. Discussion	• No Board discussion	
e. DUR Board Recommendations	• With no further Board discussion, a motion was placed before the Board.	• A motion was made by Dr. Waite and seconded by Dr. Unruh to accept the SRS recommendation for Atorvastatin (Lipitor®) and Simvastatin (Zocor®) to be the Preferred HMG-CoA Reductase Inhibitors-Statins, and PA required for Fluvastatin (Lescol®), Lovastatin (Mevacor®, Altacor®, generic
TOPIC	**DISCUSSION**	**DECISION/ACTION**

HMG-CoA Reductase Inhibitors - Continued		equivalents), Pravastatin (Pravachol®, Pravigard Pac®), and Rosuvastatin (Crestor®) with PA criteria of medical intolerance to Preferred Drug, or inadequate response to Preferred Drug, or absence of appropriate formulation or indication of the drug. It was also decided to remove "please specify" from the inadequate response portion of the PA form. The motion carried unanimously by roll call.
3. Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) **a. PDL Advisory Committee Recommendations**	• Dr. Burke stated that the PDL Committee found clinical equivalence in all NSAIDs.	
b. SRS Proposal for Preferred Drugs and PA Criteria	• Mary stated that the recommendation from SRS is for (Nalfon®), Flurbiprofen (Ansaid®), Meclofenamate Diclofenac Potassium (Cataflam®), Diclofenac Soduim (Voltaren®, Voltaren XR®), Etodolac (Lodine®, Lodine XL®), Fenoprofen (Meclomen®), Ibuprofen (Motrin®, Advil®), Ketoprofen (Orudis®, Orudis KT®, Oruvail® Toradol® (limited to 5 day supply)), Maproxen (Aleve®, Anaprox®, Naprosyn®, EC-Naprosyn®, Naprelan®), Oxaprozin (Daypro®), Sulindac (Clinoril®), and Tolmetin (Tolectin®, TolectinDS®) to be Preferred NSAIDS, and PA required for Diclofenac/Misoprostol (Arthrotec®), Indomethacin (Indocin®), Meloxicam (Mobic®), Nabumetone (Relfen®), and Piroxicam (Feldene®).	
c. Public Comment	• No public comment.	
d. Discussion	• No Board discussion	
TOPIC	**DISCUSSION**	**DECISION/ACTION**

NSAIDS-Con't **e. DUR Board Recommendations**	• With no further Board discussion, a motion was placed before the Board.	• A motion was made by Dr. Bryant and seconded by Dr. Unruh to accept the SRS recommendation for Diclofenac Potassium (Cataflam®), Diclofenac Soduim (Voltaren®, Voltaren XR®), Etodolac (Lodine®, Lodine XL®), Fenoprofen (Nalfon®), Flurbiprofen (Ansaid®), Meclofenamate (Meclomen®), Ibuprofen (Motrin®, Advil®), Ketoprofen (Orudis®, Orudis KT®, Oruvail® Toradol® (limited to 5 day supply)), Maproxen (Aleve®, Anaprox®, Naprosyn®, EC-Naprosyn®, Naprelan®), Oxaprozin (Daypro®), Sulindac (Clinoril®), and Tolmetin (Tolectin®, TolectinDS®) to be Preferred NSAIDS, and PA required for Diclofenac/Misoprostol (Arthrotec®), Indomethacin (Indocin®), Meloxicam (Mobic®), Nabumetone (Relfen®), and Piroxicam (Feldene®) with PA criteria of medical intolerance to Preferred Drug, or inadequate response to Preferred Drug, or absence of appropriate formulation or indication of the drug. It was also decided to remove "please specify" from the inadequate response portion of the PA form. The motion carried unanimously by roll call.
B. Update from Heritage	• Chris Johnson (Heritage Information Systems) presented a slide presentation regarding drug regimen simplifications. • Craig Boon (Heritage Information Systems) presented a slide presentation regarding past interventions. Dr. Burke requested placing this information in the DUR Newsletter. Vicki suggested that the Drug Regimen Simplifications should be the next population based intervention, the Pediatric intervention regarding SSRI's will be mailed out soon.	• A motion was made by Dr. Schewe and
TOPIC	**DISCUSSION**	**DECISION/ACTION**

Update from Heritage – Con't	• Craig (Heritage) stated that he should have some outcome results of the past interventions by the next meeting.	seconded by Dr. Bryant for the next intervention to be Drug Regimen Simplification. The motion carried unanimously by roll call.
C. Additional Comments	• Vicki stated that the DUR website is progressing, we are planning on having the next meeting packets available online instead of at Kinko's.	
VI. Meeting Adjournment	• There being no further discussion, a motion to adjourn was placed before the Board.	• A motion was made by Dr. Grauer and seconded by Dr. Schewe to adjourn the meeting. The motion carried unanimously by roll call. The open meeting was adjourned at 12:15 p.m.

Filename: 07-14-04 DUR Minutes.doc
Directory: C:\DOCUME~1\userii\LOCALS~1\Temp\GWViewer
Template: C:\Documents and Settings\userii\Application Data\Microsoft\Templates\Normal.dot
Title: DRUG UTILIZATION REVIEW BOARD
Subject:
Author: localadmin
Keywords:
Comments:
Creation Date: 5/18/2004 7:45 AM
Change Number: 33
Last Saved On: 10/13/2004 10:23 AM
Last Saved By: erica miller
Total Editing Time: 2,371 Minutes
Last Printed On: 10/15/2004 3:15 PM
As of Last Complete Printing
Number of Pages: 14
Number of Words: 3,306 (approx.)
Number of Characters: 17,527 (approx.)